# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION

MDL No. 1456

CIVIL ACTION: 01-CV-12257-PBS

Judge Patti B. Saris

THIS DOCUMENT RELATES TO ALL CLASS ACTIONS

# GLAXOSMITHKLINE'S ANSWER TO PLAINTIFFS' THIRD AMENDED MASTER CONSOLIDATED CLASS ACTION COMPLAINT

Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline<sup>1</sup> ("GSK"), for its Answer to Plaintiffs' Third Amended Master Consolidated Class Action Complaint (the "Third AMCC") filed on October 17, 2005, states:

#### **Preface**

The Third AMCC improperly and repetitively refers to GSK and certain other defendants and third parties on a collective basis, failing to plead with requisite particularity allegations against GSK or other defendants or third parties. Intentionally ambiguous pleading is improper and insufficient to apprise GSK in any meaningful sense of the allegations asserted against it. GSK has nevertheless attempted to respond to Plaintiffs' allegations to the extent possible under

SmithKline Beecham Corporation, d/b/a GlaxoSmithKline, is one of the three defendants comprising the so-called "GSK Group" in the Third AMCC. Named defendant GlaxoSmithKline, plc, a foreign holding company, has not yet been properly served under the Hague Convention and no appearance has been made on its behalf. Named defendant Glaxo Wellcome, Inc. no longer exists, as it was previously merged into SmithKline Beecham Corporation to form SmithKline Beecham Corporation, d/b/a GlaxoSmithKline, and therefore no appearance has been entered on its behalf either.

the circumstances. To the extent allegations refer to the knowledge, conduct or actions of other defendants or entities, GSK is generally without knowledge or information sufficient to form a belief as to the truth of those allegations and, on that basis, GSK denies those allegations. GSK states that it is answering Plaintiffs' allegations on behalf of itself only, even when Plaintiffs' allegations refer to alleged conduct by GSK and other persons or entities.

The Third AMCC improperly mixes factual allegations with inflammatory rhetoric so as to make it virtually impossible to respond meaningfully. Many of the allegations of the Third AMCC are vague or conclusory. The Third AMCC also includes terms which are undefined and which are susceptible of different meanings.

The Third AMCC also contains purported quotations from a number of sources, many of which are unidentified. If any of the quotations originate in documents protected by the attorney-client privilege, the work-product doctrine or the joint-defense privilege, GSK reserves the right to assert such privileges, hereby moves to strike such references and demands return of any such documents that Plaintiffs may have in their possession, custody or control. In answering allegations consisting of quotations, an admission that the material quoted was contained in a document or was uttered by the person or entity quoted shall not constitute an admission that the substantive content of the quote is or is not true or that the material is relevant or admissible in this action.

GSK denies each and every allegation contained in the Third AMCC, except as specifically herein admitted, and any factual averment admitted herein is admitted only as to the specific facts and not as to any conclusions, characterizations, implications, innuendos or speculations which are contained in any averment or in the Third AMCC as a whole. Moreover,

GSK specifically denies any allegations contained in headings, footnotes, the Table of Contents or unnumbered paragraphs in the Third AMCC.

These comments and objections are incorporated, to the extent appropriate, into each numbered paragraph of this Answer.

# I. INTRODUCTION

- 1. GSK admits that Plaintiffs seek to bring this action as alleged in Paragraph 1 of the Third AMCC. GSK denies that Plaintiffs are entitled to maintain this action in the manner alleged.
- 2. GSK denies the existence of, or its participation in, any "conspiracy" as alleged in Paragraph 2 of the Third AMCC. To the extent the allegations in Paragraph 2 of the Third AMCC allege a conspiracy between GSK and various publishing entities, no response is required because these allegations, which formed the basis of Count I of the Third AMCC, were dismissed with prejudice by the Court's Order dated February 25, 2004. To the extent the allegations in Paragraph 2 of the Third AMCC refer to the knowledge, conduct or actions of persons or entities other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.
- 3. To the extent the allegations in Paragraph 3 of the Third AMCC are directed to persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations and, therefore, denies those allegations. GSK admits that it manufactures certain medicines that are covered under Medicare Part B, and that Congress has mandated that Medicare Part B reimbursements be based, in part, upon AWP. GSK admits that it reports certain pricing information for its medicines to pharmaceutical industry pricing publications. GSK admits that AWPs for its medicines

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published in trade publications are typically higher than the prices ultimately paid by providers purchasing such medicines from wholesalers and distributors. GSK denies the remaining allegations in Paragraph 3 of the Third AMCC that pertain to it.

- 4. To the extent the allegations in Paragraph 4 of the Third AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. GSK admits that Congress has mandated that Medicare Part B reimbursements be based, in part, upon AWP, and further admits that Medicare Part B medicines are generally, but not always, administered in a healthcare provider's office. GSK denies the remaining allegations in Paragraph 4 of the Third AMCC that pertain to it.
- 5. GSK denies the existence of, and its participation in, any "AWP scheme" as alleged in Paragraph 5 of the Third AMCC. To the extent the allegations in Paragraph 5 of the Third AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. GSK denies the remaining allegations in Paragraph 5 of the Third AMCC that pertain to it.
- 6. To the extent the allegations in Paragraph 6 of the Third AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. GSK admits that Plaintiffs purport to bring this action as alleged in Paragraph 6 of the Third AMCC, but GSK denies that Plaintiffs are entitled to maintain this action in the manner alleged. GSK denies the remaining allegations in Paragraph 6 of the Third AMCC that pertain to it.

- 7. GSK denies the existence of, and its participation in, any "high profit scheme" as alleged in Paragraph 7 of the Third AMCC. To the extent the allegations in Paragraph 7 of the Third AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. GSK denies the remaining allegations in Paragraph 7 of the Third AMCC that pertain to it.
- 8. Answering Paragraph 8 of the Third AMCC, GSK admits that Plaintiffs have filed attachments to the Third AMCC. To the extent the allegations in Paragraph 8 of the Third AMCC are deemed to include allegations against GSK, they are denied.

#### II. JURISDICTION AND VENUE

- 9. GSK denies that it has violated the Racketeer Influenced and Corrupt Organization Act ("RICO"), 18 U.S.C. §§ 1961-68, as alleged in Paragraph 9 of the Third AMCC, denies that there exists any basis in fact or law for the institution or maintenance of this action against GSK, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 9 of the Third AMCC as to the other parties. In addition, to the extent that Paragraph 9 of the Third AMCC contains conclusions of law, GSK states that no response is required.
- 10. GSK denies that it has violated any state law claims as alleged in Paragraph 10 of the Third AMCC, and denies that there exists any basis in fact or law for the institution or maintenance of this action against GSK. In addition, to the extent that Paragraph 10 of the Third AMCC contains conclusions of law, GSK states that no response is required.
- 11. GSK denies the allegations in Paragraph 11 of the Third AMCC to the extent that they are directed at GSK, except admits that Plaintiffs allege that venue is proper in this judicial

district. GSK denies that there exists any basis in fact or law for the institution or maintenance of this action against GSK, and specifically denies the existence of, and its participation in, any alleged "fraudulent marketing scheme." In addition, to the extent that Paragraph 11 of the Third AMCC contains conclusions of law, GSK states that no response is required.

12. GSK admits the allegations in Paragraph 12 of the Third AMCC.

# III. PARTIES

- 13-54. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 13 through 54 of the Third AMCC and, therefore, denies those allegations.
- 55-59. GSK admits that Plaintiffs VPIRG, WCA, StateWide, CANY and CCJ purport to bring this action as alleged in Paragraphs 55 through 59 of the Third AMCC, but GSK denies that these Plaintiffs have standing to bring the alleged action. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraphs 55 through 59 of the Third AMCC and, therefore, denies those allegations.
- 60-61. To the extent the allegations in Paragraphs 60 through 61 of the Third AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. GSK denies the remaining allegations in Paragraphs 60 through 61 of the Third AMCC that pertain to it. GSK denies the existence of, or its participation in, any "conspiracy" as alleged in Paragraph 61 of the Third AMCC.
- 62-109. The allegations in Paragraphs 62 through 109 of the Third AMCC are directed to other defendants and require no response from GSK. To the extent the allegations in Paragraphs

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62 through 109 of the Third AMCC are deemed to include allegations against GSK, they are denied.

- 110. In response to Paragraph 110 of the Third AMCC, GSK admits only that GlaxoSmithKline plc is an English holding company headquartered in Middlesex, England, and that it acquired the stock of SmithKline Beecham plc and Glaxo Wellcome plc in December 2000. Except as so admitted, GSK denies the remaining allegations of this Paragraph. GSK specifically denies that GlaxoSmithKline plc had any involvement with the matters alleged in the Third AMCC. GSK further specifically denies that GlaxoSmithKline plc's "operational headquarters are located at One Franklin Plaza, 16th and Race Streets, Philadelphia, Pennsylvania."
  - 111. GSK admits the allegations of Paragraph 111 of the Third AMCC.
- 112. GSK denies the allegations of Paragraph 112 of the Third AMCC. By way of further answer, GSK states that Glaxo Wellcome, Inc. was merged into SmithKline Beecham Corporation in March 2001 and no longer exists as a corporation.
- 113. In response to the allegations of Paragraph 113 of the Third AMCC, GSK admits only that Plaintiffs refer to GlaxoSmithKline plc, SmithKline Beecham Corporation, and Glaxo Wellcome, Inc. as "GSK Group" in the Third AMCC. Except as so admitted, GSK denies the remaining allegations of this Paragraph and incorporates its answers above concerning Glaxo Wellcome, Inc. and GlaxoSmithKline plc. GSK further states that Plaintiffs have failed to effect valid service of process on either GlaxoSmithKline plc or Glaxo Wellcome, Inc.
- 114. In response to the allegations of Paragraph 114 of the Third AMCC, GSK admits only that it is a pharmaceutical company. Except as so admitted, GSK denies the remaining allegations of this Paragraph. By way of further answer, the allegations in this Paragraph are

directed to other defendants not properly served with valid service of process, and therefore require no response from GSK.

115. In response to the allegations of Paragraph 115 of the Third AMCC, GSK admits that it manufactured and sold Hycamtin, Ventolin, Zofran, and Navelbine. GSK further admits that it manufactured and sold Kytril until December 22, 2000 when Kytril was sold to Hoffman-LaRoche, Inc. GSK further admits that Kytril and Zofran, although not therapeutically equivalent products as that term is used by the FDA, were and are competing antiemetics. GSK further admits that certain formulations of Hycamtin, Zofran, Navelbine, Ventolin, and Kytril were covered by Medicare Part B under certain circumstances. Except as so admitted, GSK denies the remaining allegations of this Paragraph.

116. In response to the allegations of Paragraph 116 of the Third AMCC, GSK admits only that it is named as an alleged conspirator in the Together Rx claims herein. Except as so admitted, GSK denies the remaining allegations of this Paragraph. It is specifically denied that GSK engaged in any conspiracy.

117-147. The allegations in Paragraphs 117 through 147 of the Third AMCC are directed to other defendants and require no response from GSK. To the extent the allegations in Paragraphs 117 through 147 of the Third AMCC are deemed to include allegations against GSK, they are denied.

#### IV. GENERAL ALLEGATIONS APPLICABLE TO ALL DEFENDANTS

148. To the extent the allegations in Paragraph 148 of the Third AMCC are directed to other defendants, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. GSK denies the allegations in Paragraph 148 of the Third AMCC that pertain to it.

149. Upon information and belief, GSK admits the allegations in Paragraph 149 of the Third AMCC.

150-157. To the extent the allegations in Paragraphs 150-157 of the Third AMCC refer to the knowledge, conduct, opinions or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Further answering Paragraph 150 of the Third AMCC, GSK admits that Congress has mandated that Medicare Part B reimbursements be based, in part, upon AWP. Further answering Paragraphs 151 and 152 of the Third AMCC, GSK admits that pharmaceutical industry pricing publications periodically report AWPs for prescription medicines sold in the United States. GSK states that the 1999 edition of the *Red Book* and the June 1996 Dow Jones News article cited in Paragraph 152 of the Third AMCC are the best evidence of their contents. GSK denies the remaining allegations in Paragraphs 150-157 of the Third AMCC that pertain to it, and specifically denies the existence of, and its participation in, any "AWP Scheme" as alleged in Paragraph 156 of the Third AMCC.

158-160. GSK admits the allegations in Paragraphs 158 through 160 of the Third AMCC.

- 161. In response to the allegations in Paragraph 161 of the Third AMCC, GSK admits that the reimbursement methodology for drugs covered by Medicare Part B is set forth at 42 C.F.R. § 405.517, which is the best evidence of its contents.
- 162. GSK denies the allegations in the first sentence of Paragraph 162 of the Third AMCC insofar as the source of the quoted material is unidentified. GSK denies the second sentence of Paragraph 162 of the Third AMCC insofar as 42 C.F.R. § 405.517 contains no reference to a "ceiling" on reimbursement amounts.

- 163. GSK admits the allegations in Paragraph 163 of the Third AMCC.
- 164. Answering Paragraph 164 of the Third AMCC, GSK admits that the Medicare Program has publicly announced that it would use the AWP published in independently produced pricing publications as the basis for reimbursement. GSK states that the Program Memo AB-99-63 cited in Paragraph 164 of the Third AMCC is the best evidence of its contents.
- 165. GSK states that the Program Memo AB-99-63 cited in Paragraph 165 of the Third AMCC is the best evidence of its contents.
- 166-167. GSK admits the allegations in Paragraphs 166 through 167 of the Third AMCC.
- 168. To the extent the allegations in Paragraph 168 of the Third AMCC refer to the knowledge, conduct or actions of or benefits received by persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. GSK admits that there are no government regulations describing how AWPs are calculated, nor any other statutory or regulatory definitions or descriptions of AWPs. GSK admits that it reports certain pricing information for its medicines to pharmaceutical industry pricing publications. GSK denies the remaining allegations in Paragraph 168 of the Third AMCC that pertain to it.
- 169-170. GSK states that the April 2003 OIG report cited in Paragraphs 169 through 170 of the Third AMCC is the best evidence of its contents. GSK denies that Plaintiffs have accurately characterized any alleged OIG finding, opinion, statement or conclusion, or that such are applicable to GSK.
- 171. GSK denies the allegations in Paragraph 171 of the Third AMCC, except admits that the federal government has been investigating drug marketing and pricing practices.

172-173. GSK denies the existence of, and its participation in, any "scheme" cited in Paragraph 172 of the Third AMCC. GSK states that the September 28, 2000, letter from Congressman Stark to the President of Pharmaceutical Research and Manufacturers of America cited in Paragraphs 172 through 173 of the Third AMCC is the best evidence of its contents. GSK denies that Plaintiffs have accurately characterized the findings, opinions, statements or conclusions of Congressman Stark, or that such are applicable to GSK.

174. GSK denies the allegations in Paragraph 174 of the Third AMCC, except admits that the federal government investigated drug marketing and pricing practices.

175. To the extent the allegations in Paragraph 175 of the Third AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. GSK denies the remaining allegations in Paragraph 175 of the Third AMCC that pertain to it, specifically the existence of, and its participation in, any "scheme" as alleged in Paragraph 175 of the Third AMCC.

176. To the extent the allegations in Paragraph 176 of the Third AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. GSK admits that it reported AWPs for its medicines to pharmaceutical industry pricing publications before August 2001, but GSK denies that it has done so since. GSK admits the remaining allegations in Paragraph 176 of the Third AMCC that pertain to it.

177-200. To the extent the allegations in Paragraphs 177 through 200 of the Third AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than

GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. GSK admits the allegations in Paragraph 186 of the Third AMCC, except denies knowledge or information sufficient to form a belief as to the truth of the allegations in the last sentence of that paragraph. GSK avers that *The Wall Street Journal* article dated March 30, 2003, referenced in Paragraph 194 of the Third AMCC, is the best evidence of its content, which speaks for itself. GSK denies the remaining allegations in Paragraphs 177 through 200 of the Third AMCC that pertain to it, including the existence of, and its participation in, any "scheme" as alleged in Paragraphs 177 and 179 of the Third AMCC.

201. GSK admits that Plaintiffs purport to quote from an unidentified "industry consultant" as alleged in Paragraph 201 of the Third AMCC, but GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 201 of the Third AMCC and, therefore, denies those allegations.

202-207. To the extent the allegations in Paragraphs 202-207 of the Third AMCC and its subparts refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. GSK states that the *Red Book* and the unidentified DOJ report cited in Paragraph 203 the AMCC and the pleadings cited in Paragraphs 205 through 206 of the Third AMCC and subparts are the best evidence of their contents. To the extent the allegations in Paragraphs 202 through 207 of the Third AMCC are deemed to include allegations against GSK, they are denied.

208. To the extent the allegations in Paragraph 208 of the Third AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without

knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. GSK states the 2003 CMS document cited in Paragraph 208 of the Third AMCC is the best evidence of its contents. GSK denies that Plaintiffs have accurately characterized any alleged CMS finding, opinion, statement or conclusion. GSK admits that it sells its medicines in a competitive market and, as such, takes steps to keep certain information relating to its medicines confidential. GSK denies the remaining allegations in Paragraph 208 of the Third AMCC that pertain to it.

209-212. To the extent the allegations in Paragraphs 209 through 212 of the Third AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. GSK denies the allegations in Paragraphs 209-212 of the Third AMCC that pertain to it.

213. In response to the allegations in Paragraph 213 of the Third AMCC, GSK denies that Plaintiffs lacked inquiry or other notice of the issues associated with reliance on AWPs as a pricing benchmark. GSK specifically avers, to the contrary, that such issues were well known for more than a decade before Plaintiffs elected to bring this suit.

214-215. The allegations in Paragraphs 214 through 215 of the Third AMCC state legal conclusions to which no response is required. To the extent a response is required, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations in Paragraphs 214 through 215 of the Third AMCC that refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, and, therefore, GSK denies those allegations. GSK denies the remaining allegations in Paragraphs 214 through 215 of the Third AMCC that pertain to it.

#### V. EXAMPLES OF SPECIFIC UNLAWFUL CONDUCT

216. To the extent the allegations in Paragraph 216 of the Third AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. GSK denies the remaining allegations in Paragraph 216 of the Third AMCC that pertain to it.

217-391. The allegations in Paragraphs 217 through 391 of the Third AMCC are directed to other defendants and require no response from GSK. To the extent allegations in Paragraphs 217 through 391 of the Third AMCC are deemed to include allegations against GSK, they are denied.

392. In response to the allegations of Paragraph 392 of the Third AMCC, GSK admits only that Plaintiffs seek recovery as described, but denies that Plaintiffs are entitled to such recovery, and denies that GSK is in any way liable to Plaintiffs. Except as so admitted, GSK denies the remaining allegations of this Paragraph.

393. In response to the allegations of Paragraph 393 of the Third AMCC, GSK admits only that, in response to subpoenas and/or requests for information, it has engaged in discussions with and provided documents and/or information with respect to certain products to the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for Texas, the Attorney General for California, and the Attorney General for Nevada, none of which has resulted in a finding or admission of liability. Except as so admitted, GSK denies the remaining allegations of this Paragraph.

394. GSK denies the allegations of Paragraph 394 of the Third AMCC.

395. In response to the allegations of Paragraph 395 of the Third AMCC, GSK admits only that Medicare and some private insurers reimburse for prescription drugs based on some percentage of the AWP reported by third-party publishing services, such as First Databank Inc. and Facts and Comparisons. Except as so admitted, GSK denies the remaining allegations of this Paragraph. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.

396. GSK denies the allegations of Paragraph 396 of the Third AMCC. It is specifically denied that the document referred to in this Paragraph was prepared by Glaxo Wellcome, Inc. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.

397. GSK denies the allegations in Paragraph 397 of the Third AMCC. To the extent the allegations of this Paragraph are directed to other defendants, no response is required from GSK and GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations.

398. In response to the allegations of Paragraph 398 of the Third AMCC, GSK admits only that Medicare and some private insurers reimburse for prescription drugs based on some percentage of the AWP reported by third-party publishing services, such as First Databank Inc. and Facts and Comparisons. Except as so admitted, GSK denies the remaining allegations of this Paragraph. It is specifically denied that the document referred to in this Paragraph was prepared by Glaxo Wellcome, Inc. To the extent the allegations in this Paragraph refer to a document, that

document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.

- 399. GSK denies the allegations of Paragraph 399 of the Third AMCC. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
  - 400. GSK denies the allegations of Paragraph 400 of the Third AMCC.
- 401. In response to the allegations of Paragraph 401 of the Third AMCC, GSK admits that Zofran and Kytril are both antiemetics prescribed by physicians for chemotherapy-induced nausea and vomiting. GSK further admits that Zofran and Kytril, although not therapeutically equivalent products as that term is used by the FDA, were and are competing antiemetics. GSK states that Kytril was sold to Hoffman-LaRoche, Inc. in December 22, 2000. Except as so admitted, GSK denies the remaining allegations of this Paragraph.
- 402. GSK denies the allegations of Paragraph 402 of the Third AMCC. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
- 403. To the extent the allegations of Paragraph 403 of the Third AMCC refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
- 404. GSK denies the allegations of Paragraph 404 of the Third AMCC. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any

allegations inconsistent with the plain meaning and clear terms of the complete document are denied.

405. GSK denies the allegations of Paragraph 405 of the Third AMCC. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.

406. GSK denies the allegations of Paragraph 406 of the Third AMCC. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.

407. GSK denies the allegations of Paragraph 407 of the Third AMCC. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.

408. GSK denies the allegations of Paragraph 408 of the Third AMCC. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.

409. GSK denies the allegations of Paragraph 409 of the Third AMCC. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.

- 410. In response to the allegations of Paragraph 410 of the Third AMCC, GSK admits only that, in March 1996, Glaxo Wellcome, Inc. increased its Net Wholesale Price (NWP) and Average Wholesale Price (AWP) for Zofran by 4.9% for NDCs 00173-0442-00 and 00173-0461-00 and by 8.6% for NDC 00173-0442-02, and SmithKline Beecham Corporation increased its Wholesale Purchase Price (WPP) and Suggested List Price (SLP) for Kytril by 4.8%. Except as so admitted, GSK denies the remaining allegations of this Paragraph. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
- 411. GSK denies the allegations of Paragraph 411 of the Third AMCC. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
- 412. GSK denies the allegations of Paragraph 412 of the Third AMCC. It is specifically denied that the document referred to in this paragraph was prepared by Glaxo Wellcome, Inc. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
- 413. GSK denies the allegations of Paragraph 413 of the Third AMCC. It is specifically denied that the documents referred to in this Paragraph were prepared by Glaxo Wellcome, Inc. To the extent the allegations in this Paragraph refer to documents, those documents speak for themselves. Any allegations inconsistent with the plain meaning and clear terms of the complete documents are denied.

- 414. GSK denies the allegations of Paragraph 414 of the Third AMCC. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
- 415. GSK denies the allegations of Paragraph 415 of the Third AMCC. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
- 416. GSK denies the allegations of Paragraph 416 of the Third AMCC. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
- 417. GSK denies the allegations of Paragraph 417 of the Third AMCC. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
- 418. In response to the allegations of Paragraph 418 of the Third AMCC, GSK admits only that Kytril was sold to Hoffman-LaRoche, Inc. in December 22, 2000. Except as so admitted, GSK denies the remaining allegations of this Paragraph. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
- 419. GSK denies the allegations of Paragraph 419 of the Third AMCC. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any

allegations inconsistent with the plain meaning and clear terms of the complete document are denied.

- 420. GSK denies the allegations of Paragraph 420 of the Third AMCC. To the extent the allegations in this Paragraph refer to documents, those documents speak for themselves. Any allegations inconsistent with the plain meaning and clear terms of the complete documents are denied.
  - 421. GSK denies the allegations of Paragraph 421 of the Third AMCC.
- 422. To the extent the allegations of Paragraph 422 of the Third AMCC refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
- 423. GSK denies the allegations of Paragraph 423 of the Third AMCC. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
- 424. GSK denies the allegations of Paragraph 424 of the Third AMCC. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
  - 425. GSK denies the allegations of Paragraph 425 of the Third AMCC.
  - 426. GSK denies the allegations of Paragraph 426 of the Third AMCC.
- 427. GSK denies the allegations of Paragraph 427 of the Third AMCC. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any

allegations inconsistent with the plain meaning and clear terms of the complete document are denied.

- 428. GSK denies the allegations of Paragraph 428 of the Third AMCC. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
- 429. In response to the allegations of Paragraph 429 of the Third AMCC, GSK admits that Kytril was effective when dosed based on the weight of the patient and, as a result, in some cases, physicians may have used less than 1 mg of the single dose vial. GSK further admits that, beginning in July 1997, it manufactured and sold a 4 mg multi-dose vial of Kytril. Except as so admitted, GSK denies the remaining allegations of this Paragraph. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
  - 430. GSK denies the allegations of Paragraph 430 of the Third AMCC.
- 431. GSK denies the allegations of Paragraph 431 of the Third AMCC. To the extent the allegations in this Paragraph refer to a report by the Department of Health and Human Services, that report speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the report are denied. It is specifically denied that the table in this Paragraph and/or the report by the Department of Health and Human Services accurately calculated the AWP, the "actual AWP," the "difference," and/or the "percentage spread."
  - 432. GSK denies the allegations of Paragraph 432 of the Third AMCC.
- 433-551. The allegations in Paragraphs 433 through 551 of the Third AMCC are directed to other defendants and require no response from GSK. To the extent allegations in Paragraphs

433 through 551 of the Third AMCC are deemed to include allegations against GSK, they are denied.

# VI. PLAINTIFFS' CLAIM FOR DAMAGES

552. GSK denies that Plaintiffs have suffered damages or injuries as alleged in Paragraph 552 of the Third AMCC. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 552 of the Third AMCC and, therefore, denies those allegations.

# VII. CLASS ACTION ALLEGATIONS FOR THE AWP PAYOR SCHEME

553-554. GSK admits that Plaintiffs purport to bring this action as alleged in Paragraphs 553 through 554 of the Third AMCC, but GSK denies that Plaintiffs are entitled to maintain this action in the manner alleged, or that Plaintiffs have pled a proper class or named proper class representatives.

555-562. The allegations in Paragraphs 557 through 562 of the Third AMCC state legal conclusions to which no answer is required. GSK denies, however, that Plaintiffs have pled a proper class or named proper class representatives, or that the allegations against GSK have any basis in law or fact. Further answering, GSK denies that Plaintiffs or any putative class members have suffered damages or injuries as alleged in Paragraphs 555 through 562 of the Third AMCC.

#### COUNT I

# VIOLATIONS OF 18 U.S.C. § 1962(C)

563-591. The Court dismissed Count I in its Order dated February 25, 2004. Accordingly, GSK does not respond to Paragraphs 563 through 591 of the Third AMCC. To the extent a response is required, GSK denies all allegations contained within Count I of the Third AMCC.

#### COUNT II

# **VIOLATIONS OF 18 U.S.C. § 1962(C)**

- 592. Answering Paragraph 592 of the Third AMCC, GSK re-alleges and incorporates its responses to the allegations in Paragraphs 1 through 591 of the Third AMCC.
- 593. To the extent the allegations in Paragraph 593 of the Third AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. GSK admits that Plaintiffs purport to bring this action and to seek relief under Count II of the Third AMCC as alleged in Paragraph 593, but GSK denies that Plaintiffs are entitled to maintain this action as alleged or to any relief against GSK under Count II. GSK denies the remaining allegations in Paragraph 593 of the Third AMCC.
- 594. The allegations in Paragraph 594 of the Third AMCC state a legal conclusion to which no answer is required. GSK denies, however, that Plaintiffs have pled a proper class.
- 595. To the extent the allegations in Paragraph 595 of the Third AMCC and subparts state legal conclusions, GSK avers that no answer is required. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 595 and subparts and, therefore, denies those allegations.
- 596-600. GSK denies the existence of, or its participation in, any "enterprise," "AWP Scheme," or "hidden-profitmaking scheme" as alleged in Paragraphs 596 through 600 of the Third AMCC. To the extent the allegations in Paragraphs 596 through 600 of the Third AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. GSK states that the unidentified "industry

report" cited in Paragraph 600 of the Third AMCC is the best evidence of its contents. GSK denies that Plaintiffs have accurately characterized any alleged "industry report" finding, opinion, statement or conclusion. GSK denies the remaining allegations in Paragraphs 596 through 600 that pertain to it.

601-624. GSK denies the existence of, or its participation in, any "enterprise," "AWP spread scheme," "AWP Scheme," "The GSK Group Manufacturer-PBM Enterprise" and/or "Manufacturer-PBM Enterprise" as alleged in Paragraphs 601 through 624 of the Third AMCC. To the extent the allegations in Paragraphs 601 through 624 of the Third AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. To the extent the allegations in Paragraphs 601 through 624 of the Third AMCC include allegations against GSK, they are denied.

#### **COUNT III**

#### **DECLARATORY AND OTHE RELIEF**

625. Answering Paragraph 625 of the Third AMCC, GSK re-alleges and incorporates its responses to the allegations in Paragraphs 1 through 624 of the Third AMCC. GSK admits that Plaintiffs purport to bring this action as alleged in Paragraphs 625 of the Third AMCC, but GSK denies that Plaintiffs are entitled to maintain this action in the manner alleged, or that Plaintiffs have pled a proper class or named proper class representatives.

626. The allegations in Paragraph 626 of the Third AMCC state legal conclusions to which no response is required. To the extent a response is required, GSK denies that Plaintiffs have standing to bring this action, and denies that an actual case and controversy exists. To the extent the allegations in Paragraph 626 of the Third AMCC refer to the knowledge, conduct or

actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. GSK denies the allegations in Paragraph 626 of the Third AMCC that pertain to it.

- 627. GSK denies the allegations in Paragraph 627 of the Third AMCC to the extent they are directed at GSK, and denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 627 as to the other parties and entities.
- 628. GSK states that Paragraph 628 of the Third AMCC consists of a conclusion of law to which no response is required, otherwise denies the allegations in Paragraph 628 to the extent that they are directed at GSK, and denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 628 as to the other parties and entities.

# **COUNT IV**

#### **CONSUMER PROTECTION STATUTES**

- 629. Answering Paragraph 629 of the Third AMCC, GSK re-alleges and incorporates its responses to the allegations in Paragraphs 1 through 628 of the Third AMCC. GSK admits that Plaintiffs purport to bring this action to preserve Plaintiffs' rights to appease the home state issues as alleged in Paragraph 629, but GSK denies that Plaintiffs are entitled to maintain this action as alleged or to any relief against GSK under Count IV.
- 630. GSK admits that Plaintiffs purport to bring this action and to seek relief under Count IV of the Third AMCC as alleged in Paragraph 630, but GSK denies that Plaintiffs are entitled to maintain this action as alleged or to any relief against GSK under Count IV.
- 631-636. To the extent the allegations in Paragraph 631 of the Third AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without

knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. GSK admits that certain states have enacted consumer protection laws, but GSK denies that it has violated such laws or that Plaintiffs or any putative class members are entitled to relief under such laws. GSK denies the remaining allegations in Paragraphs 631 through 636 of the Third AMCC and subparts that pertain to it. GSK further denies that Plaintiffs or any putative class members have suffered damages or injuries as alleged in Paragraphs 634 and 636 of the Third AMCC.

#### **COUNT V**

# <u>CONSUMER PROTECTION LAWS -</u> MEDICARE PART B CO-PAY SUB-CLASS

637. Answering Paragraph 637 of the Third AMCC, GSK re-alleges and incorporates its responses to the allegations in Paragraphs 1 through 636 of the Third AMCC.

638-640. GSK admits that Plaintiffs purport to bring this action and to seek relief under Count V of the Third AMCC as alleged in Paragraphs 638 through 640, but GSK denies that Plaintiffs are entitled to maintain this action as alleged or to any relief against GSK under Count V. Furthermore, GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 639 of the Third AMCC and, therefore, denies those allegations. Moreover, the allegations in Paragraphs 638 through 640 of the Third AMCC state legal conclusions to which no answer is required. GSK further denies that in Paragraph 639 Plaintiffs have pled a proper class or named proper class representatives, or that the allegations against GSK have any basis in law or fact. Further answering, GSK denies that Plaintiffs or any putative class members have suffered damages or injuries as alleged in Paragraphs 638 through 640 of the Third AMCC. GSK denies that Plaintiffs or any putative class members are entitled to relief as alleged in Paragraph 640.

641-642. To the extent the allegations in Paragraphs 641 through 642 of the Third AMCC and subparts refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. GSK admits that certain states have enacted consumer protection laws, but GSK denies that it has violated such laws or that Plaintiffs or any putative class members are entitled to relief under such laws. Additionally, the allegations in Paragraphs 641 through 642 of the Third AMCC state legal conclusions to which no answer is required. GSK denies the remaining allegations in Paragraphs 641 through 642.

- 643. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 643 of the Third AMCC and, therefore, denies those allegations.
- 644. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 651 of the Third AMCC and, therefore, denies those allegations.

#### **COUNT VI**

# CONSUMER PROTECTION LAWS – THIRD PARTY PAYORS PART B MEDIGAP CLASS

645. Answering Paragraph 645 of the Third AMCC, GSK re-alleges and incorporates its responses to the allegations in Paragraphs 1 through 644 of the Third AMCC.

646-647. GSK admits that Plaintiffs purport to bring this action and to seek relief under Count VI of the Third AMCC as alleged in Paragraphs 646 through 647, but GSK denies that Plaintiffs are entitled to maintain this action as alleged or to any relief against GSK under Count VI. Furthermore, GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 646 of the Third AMCC and, therefore, denies those allegations. GSK denies that Plaintiffs or any putative class members are entitled to relief as alleged in Paragraph 647. Moreover, the allegations in Paragraphs 646 through 647 of the Third

AMCC state legal conclusions to which no answer is required. GSK additionally denies that in Paragraph 646 Plaintiffs have pled a proper class or named proper class representatives, or that the allegations against GSK have any basis in law or fact. Further answering, GSK denies that Plaintiffs or any putative class members have suffered damages or injuries as alleged in Paragraphs 646 through 647 of the Third AMCC.

648-649. To the extent the allegations in Paragraphs 648 through 649 of the Third AMCC and subparts refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. GSK admits that certain states have enacted consumer protection laws, but GSK denies that it has violated such laws or that Plaintiffs or any putative class members are entitled to relief under such laws. Additionally, the allegations in Paragraphs 648 through 649 of the Third AMCC state legal conclusions to which no answer is required. GSK denies the remaining allegations in Paragraphs 648 through 649.

- 650. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 650 of the Third AMCC and, therefore, denies those allegations.
- 651. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 651 of the Third AMCC and, therefore, denies those allegations.

# **COUNT VII**

# CONSUMER PROTECTION LAWS - PHYSICIAN - ADMINISTERED CLASS FOR CONSUMERS AND TPPS

652. Answering Paragraph 652 of the Third AMCC, GSK re-alleges and incorporates its responses to the allegations in Paragraphs 1 through 651 of the Third AMCC.

653. GSK admits that Plaintiffs purport to bring this action and to seek relief under Count VII of the Third AMCC as alleged in Paragraph 653, but GSK denies that Plaintiffs are entitled to maintain this action as alleged or to any relief against GSK under Count VII.

654-655. GSK admits that Plaintiffs purport to bring this action and to seek relief under Count VII of the Third AMCC as alleged in Paragraphs 654 through 655, but GSK denies that Plaintiffs are entitled to maintain this action as alleged or to any relief against GSK under Count VII. Furthermore, GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 654 through 655 of the Third AMCC and, therefore, denies those allegations. Moreover, the allegations in Paragraphs 654 through 655 of the Third AMCC state legal conclusions to which no answer is required. GSK denies, however, that in Paragraphs 654 through 655 Plaintiffs have pled a proper class or named proper class representatives, or that the allegations against GSK have any basis in law or fact. Further answering, GSK denies that Plaintiffs or any putative class members have suffered damages or injuries as alleged in Paragraphs 654 through 655 of the Third AMCC.

656. GSK admits that Plaintiffs purport to bring this action and to seek relief under Count VII of the Third AMCC as alleged in Paragraph 656, but GSK denies that Plaintiffs are entitled to maintain this action as alleged or to any relief against GSK under Count VII.

657-658. To the extent the allegations in Paragraphs 657 through 658 of the Third AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. GSK admits that certain states have enacted consumer protection laws, but GSK denies that it has violated such laws or that Plaintiffs

or any putative class or subclass members are entitled to relief under such laws as alleged in Paragraphs 657 and 658.

659. To the extent the allegations in Paragraph 659 of the Third AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Moreover, the allegations in Paragraph 659 state legal conclusions to which no response is required. GSK denies the remaining allegations in Paragraph 659.

#### **COUNT IX**

# CIVIL CONSPIRACY (AGAINST ALL DEFENDANTS IDENTIFIED HEREIN FOR CONSPIRING WITH PBMS)

- 660. Answering Paragraph 660 of the Third AMCC, GSK re-alleges and incorporates its responses to the allegations in Paragraphs 1 through 659 of the Third AMCC.
- 661. GSK admits that Plaintiff CMHV purports to bring this action as alleged in Paragraph 661 of the Third AMCC, but GSK denies that Plaintiff CMHV is entitled to maintain this action in the manner alleged or that CMHV is a proper class representative. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 661 of the Third AMCC and, therefore, denies those allegations.
- 662-665. GSK denies the existence of, and its participation in, any "scheme," "AWP Scheme," "conspiracy" or "The GSK Group Manufacturer-PBM Conspiracies" as alleged in Paragraphs 662 through 665 of the Third AMCC. To the extent the allegations in Paragraphs 662 through 665 of the Third AMCC and subparts refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information

sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. GSK denies the remaining allegations in Paragraphs 662 though 665 of the Third AMCC and subparts that pertain to it.

666-667. GSK denies the allegations in Paragraphs 666 through 667 of the Third AMCC. Specifically, GSK denies that Plaintiffs or any putative class members have suffered damages or injuries as alleged in Paragraph 667 of the Third AMCC.

# VIII-IX: PRAYER FOR RELIEF AND DEMAND FOR JURY TRIAL

GSK denies Plaintiffs are entitled to a judgment or any other relief requested in their Prayer for Relief and "WHEREFORE" paragraph following Paragraph 667 of the Third AMCC.

#### **DEFENSES**

Without assuming the burden of proof of such defenses that it would not otherwise have, GSK affirmatively asserts the following defenses:

# **First Defense**

Plaintiffs and the putative class fail to state a claim against GSK upon which relief may be granted.

# **Second Defense**

Plaintiffs' and the putative class' claims are barred, in whole or in part, by the political question and separation of powers doctrines.

#### **Third Defense**

Plaintiffs' and the putative class' claims are barred, in whole or in part, by the filed rate doctrine.

#### **Fourth Defense**

Plaintiffs and the putative class have not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of GSK as alleged in the Third AMCC.

#### **Fifth Defense**

To the extent Plaintiffs and/or any member of the putative class obtain recovery in any other case predicated on the same factual allegations, that Plaintiff or purported class member is barred from seeking recovery against GSK based on the Third AMCC pursuant to the doctrines of res judicata and collateral estoppel, and the prohibition on double recovery for the same injury.

#### **Sixth Defense**

Plaintiffs' and the putative class' claims are barred, in whole or in part, by the First Amendment to the United States Constitution and the analogous provisions of the Constitutions of the States of California, Delaware, Florida, Illinois, Louisiana, Minnesota, New Jersey, New York, Pennsylvania, Texas, Washington and any other States whose laws are or become relevant in the course of this multidistrict litigation.

## **Seventh Defense**

Plaintiffs' and the putative class' claims are barred, in whole or in part, by the *Noerr-Pennington* doctrine to the extent that such claims are premised, in whole or in part, on alleged statements or conduct by GSK in judicial, legislative or administrative proceedings of any kind or at any level of government.

# **Eighth Defense**

Plaintiffs' and the putative class' claims are barred, in whole or in part, to the extent that Plaintiffs and the putative class members have released, settled, entered into an accord and satisfaction or otherwise compromised their claims.

#### **Ninth Defense**

Any and all actions taken by GSK with respect to any of the matters alleged in the Third AMCC were taken in good faith and in accordance with established industry practice.

## **Tenth Defense**

Plaintiffs' and the putative class' state law claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated there under.

#### **Eleventh Defense**

Plaintiffs' and the putative class' claims are preempted by the dormant Commerce Clause of the United States Constitution.

#### **Twelfth Defense**

Plaintiffs' and the putative class' claims against GSK are barred because GSK has complied with all applicable regulations of the federal and state governments.

#### **Thirteenth Defense**

Plaintiffs' and the putative class' claims against GSK are barred, in whole or in part, by the applicable statutes of limitations and repose, and by the doctrines of laches, estoppel, and waiver.

#### **Fourteenth Defense**

Plaintiffs' and the putative class' claims are barred, in whole or in part, because they violate GSK's rights under the Due Process and *Ex Post Facto* clauses of the United States Constitution, as well as all applicable state constitutions, insofar as Plaintiffs and the putative class members seek to impose liability retroactively for conduct that was not actionable at the time it occurred.

#### **Fifteenth Defense**

GSK's statements or actions were not the proximate cause or cause in fact of any injury to or alleged loss by Plaintiffs or the putative class.

# **Sixteenth Defense**

Plaintiffs and the putative class fail to state with particularity facts to support the fraud allegations, and fail to plead with particularity the fraudulent concealment and multi-source medicine allegations against GSK contained in the Third AMCC.

#### **Seventeenth Defense**

Plaintiffs and the putative class fail to allege with particularity their civil conspiracy claims against GSK as required by Fed. R. Civ. P. 9(b).

#### **Eighteenth Defense**

Plaintiffs' and the putative class' claims against GSK are barred, in whole or in part, because GSK did not make any false statements to Plaintiffs or to any members of the putative class members. As to any statement asserted against GSK that Plaintiffs and the putative class allege to be false or misleading, GSK had no reasonable grounds to believe, and did not believe at the time such a statement was made, that the statement was false or misleading.

#### **Nineteenth Defense**

Plaintiffs' and the putative class' claims against GSK are barred because GSK did not directly or indirectly conspire with any other entity or engage in any other conduct in violation of state or federal law.

#### **Twentieth Defense**

Plaintiffs' and the putative class' RICO claims against GSK are barred, in whole or in part, due to Plaintiffs' failure to properly allege a RICO enterprise as required by 18 U.S.C. § 1962(c).

# **Twenty-First Defense**

Plaintiffs' and the putative class' RICO claims against GSK are barred, in whole or in part, due to their failure to plead facts showing that GSK and the PBMs are ongoing organizations whose members function as a continuing unit and share common purposes as required by *United States v. Turkette*, 452 U.S. 576, 583 (1981).

#### **Twenty-Second Defense**

Plaintiffs' and the putative class' RICO claims against GSK are barred, in whole or in part, due to their failure to allege that GSK conducted the affairs of the alleged enterprises as required by 18 U.S.C. § 1962(c).

#### **Twenty-Third Defense**

Plaintiffs and the putative class lack standing to bring their RICO claims against GSK because they cannot show GSK directly caused their alleged injuries as required by 18 U.S.C. § 1964(c) and *Holmes v. Securities Investor Prot. Corp.*, 503 U.S. 258, 265-66, 268 (1992).

#### **Twenty-Fourth Defense**

Plaintiffs' and the putative class' civil conspiracy claims against GSK are barred, in whole or in part, by their failure to allege a concerted action as required by *Aetna Cas. Sur. Co.* 

v. P&B Autobody, 43 F.3d 1546, 1564 (1st Cir. 1994) and Grant v. John Hancock Mut. Life Ins. Co., 183 F. Supp. 2d 344, 359 (D. Mass. 2002), and/or by their failure to allege a coercive conspiracy as required by Fleming v. Dance, 22 N.E.2d 609, 611 (Mass. 1939).

#### **Twenty-Fifth Defense**

Plaintiffs' and the putative class' civil conspiracy claims against GSK are barred, in whole or in part, because they are duplicative and improper under Massachusetts law. *See Grant*, 183 F. Supp. 2d at 364.

#### **Twenty-Sixth Defense**

GSK denies that Plaintiffs and the putative class have valid consumer protection claims against GSK under California, Delaware, Florida, Illinois, Louisiana, Minnesota, New Jersey, New York, Pennsylvania, Texas, Washington or any other State whose law is or becomes relevant in the course of this multidistrict litigation. However, if such claims are found to exist, GSK pleads all available defenses under the Acts.

#### **Twenty-Seventh Defense**

Any allegedly fraudulent statements or conduct of GSK did not directly or proximately cause the alleged injuries of Plaintiffs and/or any members of the putative class as required under state consumer protection laws, including without limitation those of Florida, Illinois, Louisiana, New Jersey, New York, Pennsylvania, Texas and Washington or any other State whose law is or becomes relevant in the course of this multidistrict litigation.

# **Twenty-Eighth Defense**

GSK's conduct was neither "deceptive," "misleading," "unlawful" nor "illegal" as required under certain state consumer protection laws, including without limitation those of Delaware, Florida, Illinois, Louisiana, Minnesota, New Jersey, New York, Texas and/or

Washington or any other State whose law is or becomes relevant in the course of this multidistrict litigation.

## **Twenty-Ninth Defense**

To the extent that Plaintiffs and the putative class members attempt to seek equitable relief against GSK, they are not entitled to such relief because they have an adequate remedy at law.

#### **Thirtieth Defense**

Plaintiffs and the putative class lack standing to bring their asserted consumer protection claims against GSK under certain state consumer protection laws, including without limitation those of Delaware, Florida, Louisiana, New Jersey, Pennsylvania and Washington or any other State whose law is or becomes relevant in the course of this multidistrict litigation.

#### **Thirty-First Defense**

Plaintiffs and the putative class did not rely on the allegedly fraudulent statements or conduct of GSK as required under certain state consumer protection laws, including without limitation those of New York and Pennsylvania or any other State whose law is or becomes relevant in the course of this multidistrict litigation.

# **Thirty-Second Defense**

Any allegedly fraudulent statement or conduct of GSK was not consumer-oriented as required under certain consumer protection law, including without limitation that of New York or any other State whose law is or becomes relevant in the course of this multidistrict litigation.

#### **Thirty-Third Defense**

Plaintiffs' and the putative class' claims against GSK for injunctive relief were mooted by the passage of the 2003 Medicare reform legislation.

#### **Thirty-Fourth Defense**

Plaintiffs' and the putative class' claims for injunctive relief against GSK are barred by the doctrines of *in pari delicto* and/or unclean hands.

# **Thirty-Fifth Defense**

This action cannot be maintained as a class action because (1) the certification and maintenance of this action as a class would violate the separation of powers provisions of the United States Constitution and would be an unconstitutional usurpation of authority reserved to the legislative branch; (2) the claims of Plaintiffs and the putative class cannot be properly joined with one another because they did not arise out of the same transaction, occurrence, or series of transactions or occurrences; (3) the named Plaintiffs and the putative class cannot satisfy the procedural requirements of Fed. R. Civ. P. 23; (4) the questions of fact at issue are not common to the alleged class, but rather, are highly specific and will vary dramatically from person to person and entity to entity; and/or (5) class certification would violate GSK's rights provided by the Fifth, Seventh and Fourteenth Amendments to the United States Constitution as well as by the Constitutions of the States of California, Delaware, Florida, Illinois, Louisiana, Minnesota, New Jersey, New York, Pennsylvania, Texas, Washington and any other States whose laws are or become relevant in the course of this multidistrict litigation, including but not limited to GSK's right to procedural and substantive safeguards, which include traditional defenses to liability.

#### **Thirty-Sixth Defense**

To the extent that Plaintiffs and the putative class seek to assert any antitrust claims against GSK, such claims: (1) are barred because they have not suffered any antitrust injury; (2) are barred in whole or in part for lack of standing; and/or (3) should be dismissed because the alleged conspiracy does not make economic sense and is economically implausible.

#### **Thirty-Seventh Defense**

Any alleged restraints complained of in the Third AMCC are ancillary to legitimate, procompetitive activity.

## **Thirty-Eighth Defense**

GSK's conduct was not intended to have, did not have and was not likely to have had any adverse effects on competition in any relevant market.

#### **Thirty-Ninth Defense**

To the extent that Plaintiffs and the putative class seek to assert any antitrust claims against GSK under the various state antitrust statutes, such claims are barred in whole or in part to the extent those statutes (1) do not allow (or did not allow at the time the conduct was alleged herein) recovery of damages by indirect purchasers; and (2) do not govern conduct that is predominantly interstate in nature.

#### **Fortieth Defense**

To the extent that Plaintiffs and the putative class seek to assert any antitrust claims against GSK under the various state unfair trade and competition statutes, such claims are barred in whole or in part to the extent those statutes (1) do not allow (or did not allow at the time the conduct was alleged herein) recovery of damages by indirect purchasers; and (2) do not govern conduct that is predominantly intrastate in nature.

# **Forty-First Defense**

To the extent that Plaintiffs and the putative class seek to assert any antitrust claims against GSK under the various state consumer protection and consumer fraud statutes, such claims are barred in whole or in part to the extent those statutes (1) do not allow (or did not allow at the time the conduct was alleged herein) recovery of damages by indirect purchasers; and (2) do not govern conduct that is predominantly intrastate in nature.

#### **Forty-Second Defense**

To the extent that Plaintiffs and the putative class seek to assert any antitrust claims against GSK under the various state unfair trade, unfair competition, consumer protection and consumer fraud statutes, such claims are barred to the extent that (1) those claims represent an impermissible circumvention of the states' antitrust statutes; and (2) those statutes apply only to deceptive or misleading conduct and/or govern only consumer transactions.

#### **Forty-Third Defense**

Third party payor plaintiffs' and third party payor putative class members' claims against GSK are barred, in whole or in part, with respect to any alleged overcharge or supracompetitive price on the ground that third party payors passed on any effect of the alleged supracompetitive prices to their customers or employees in the form of higher premiums, co-pays or other charges.

# **Forty-Fourth Defense**

Plaintiffs' and the putative class' claims against GSK are barred, in whole or in part, with respect to any alleged overcharge or supracompetitive price because such supracompetitive price, if any, was absorbed, in whole or part, by a person and/or entity which purchased the medicine directly, and/or by an intermediate indirect purchaser, and was not passed through to the Plaintiffs and putative class members.

#### **Forty-Fifth Defense**

Plaintiffs' and the putative class' claims against GSK are barred, in whole or in part, due to their failure to join indispensable parties.

# **Forty-Sixth Defense**

Plaintiffs' and the putative class' claims against GSK are barred, in whole or in part, because they have suffered no damages as a result of the matters alleged in the Third AMCC.

#### **Forty-Seventh Defense**

Plaintiffs' and the putative class' claims are barred, in whole or in part, because any injuries sustained by Plaintiffs or the putative class were the result of intervening or superceding conduct of third parties.

#### **Forty-Eighth Defense**

Plaintiffs' and the putative class' claims against GSK for damages are barred, in whole or in part, (1) because they failed to mitigate their damages, and their failure to mitigate damages should proportionately reduce the recovery of such persons and the allocation of any fault, if any exists, attributable to GSK; (2) because they would be unjustly enriched if allowed to recover any portion of the damages alleged in the Third AMCC; (3) by the doctrine of consent and/or ratification to the extent that plaintiffs and/or putative class members have received and paid for medicines manufactured, marketed and sold by GSK after the filing of Plaintiffs' original Complaint; and (4) because they are speculative and remote and because of the impossibility of ascertaining and allocating those alleged damages.

# **Forty-Ninth Defense**

GSK is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiffs and/or the putative class, with respect to the same alleged injuries.

#### <u>Fiftieth Defense</u>

Any damages recovered by the Plaintiffs and the putative class from GSK must be limited by the applicable statutory ceilings on recoverable damages.

#### **Fifty-First Defense**

Plaintiffs and the putative class fail to allege facts or a cause of action against GSK sufficient to support a claim for attorneys' fees, treble damages and/or legal fees.

# **Fifty-Second Defense**

To the extent punitive damages are sought, Plaintiffs' and the putative class' punitive damages claims against GSK: (1) have no basis in law or fact; (2) are not recoverable because the allegations of the Third AMCC are legally insufficient to support a claim for punitive damages against GSK; (3) cannot be sustained because laws regarding the standards for determining liability for and the amount of punitive damages fail to give GSK prior notice of the conduct for which punitive damages may be imposed and the severity of the penalty that may be imposed and are void for vagueness in violation of GSK's due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and the constitutions of any applicable states' laws; (4) cannot be sustained because any award of punitive damages exceeding the limits authorized by the laws or other comparable laws would violate GSK's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the constitutions, common law and applicable states' laws; (5) cannot be sustained because an award of punitive damages in this case, combined with any prior, contemporaneous, or subsequent judgments against GSK for punitive damages arising from the design, development, manufacture, fabrication, distribution, supply, marketing, sale, or use of GSK's medicines would constitute impermissible multiple punishments for the same wrong, in violation of GSK's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would constitute double jeopardy in violation of the constitutions, common law and statutory law of any applicable states' laws; (6) cannot be sustained because any award of punitive damages without the apportionment of the award separately and severally between or among the alleged joint tortfeasors, as determined by the alleged percentage of the wrong committed by each alleged tortfeasor, would violate GSK's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the constitutions, common law and public policies of any applicable states' law; and (7) cannot be sustained because any award of punitive damages, which are penal in nature, without according GSK the same protections that are accorded to all criminal defendants, including the protection against unreasonable searches and seizures, the privilege against self-incrimination, and the rights to confront adverse witnesses, a speedy trial, and the effective assistance of counsel, would violate GSK's rights guaranteed by the Fourth, Fifth, and Sixth Amendment as incorporated into the Fourteenth Amendment to the United States Constitution and would be improper under the constitutions, common law and public policies of any applicable states' laws.

#### **Fifty-Third Defense**

To the extent punitive damages are sought, Plaintiffs' and the putative class' claim for punitive damages against GSK cannot be sustained because an award of punitive damages by a jury that: (1) is not provided constitutionally adequate standards of sufficient clarity for determining the appropriate imposition of, and the appropriate size of, a punitive damages award, (2) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment, (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part on the basis of invidiously discriminatory characteristics, including without limitation the residence, wealth, and corporate status of GSK, (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages

permissible, (5) is not properly instructed regarding Plaintiffs' and the putative class' burden of proof with respect to each and every element of a claim for punitive damages, and (6) is not subject to trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionally adequate and objective standards, would violate GSK's Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution, and would be improper under the constitutions, common law and public policies of any applicable states' laws.

#### **Fifty-Fourth Defense**

To the extent punitive damages are sought, Plaintiffs' and the putative class' claim for punitive damages against GSK cannot be sustained because an award of punitive damages that is subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount of punitive damages that may be imposed, would: (1) violate GSK's due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution; (2) violate GSK's right not to be subjected to an excessive award; and (3) be improper under the constitutions, common law and public policies of any applicable states' laws.

#### **Fifty-Fifth Defense**

GSK adopts by reference any additional applicable defense pled by any other defendant not otherwise pled herein.

#### **Fifty-Sixth Defense**

GSK hereby gives notice that it intends to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserves its right to amend its answer to assert such defense. GSK also reserves the right to assert such other and related defenses as may become available in the event of a determination that the action, or some part thereof, is governed by the substantive law of a

state other than California, Delaware, Florida, Illinois, Louisiana, Minnesota, New Jersey, New York, Pennsylvania, Texas, Washington and/or any other State whose law is or becomes relevant in the course of this multidistrict litigation.

#### WHEREFORE, GSK prays that this Court:

- 1. Dismiss the Third Amended Master Consolidated Class Action Complaint with prejudice and enter judgment in favor of GSK and against Plaintiffs;
- 2. Award GSK its costs and expenses; and
- 3. Grant such other and further relief for GSK as this Court deems just and proper.

Respectfully submitted,

**BY:** \_\_\_\_/s/ Mark D. Seltzer\_

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DATE: November 3, 2005 Counsel for SmithKline Beecham Corp. d/b/a GlaxoSmithKline ("GSK")

# **CERTIFICATE OF SERVICE**

I hereby certify that on this 3rd day of November, 2005, a true and correct copy of the foregoing document was served upon all counsel of record by electronic service pursuant to CMO No. 2, by causing a copy to be sent to File & Serve for posting and notification.

<u>/s/ Mark D. Seltzer</u> Attorney for Defendant SmithKlineBeecham

Corporation d/b/a GlaxoSmithKline